DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#17

APR 24 1992

Re: ACEL-IMUNE®
Docket No. 92E-0115

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Manbeck:

This is in regard to the application for patent term extension for U.S. Patent No. 4,455,297, filed by Takeda Chemical Industries, Ltd., under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for ACEL-IMUNE®, the human biologic product claimed by the patent.

The total length of the review period for ACEL-IMUNE® is 2,002 days. Of this time, 400 days occurred during the testing phase and 1,602 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this human biologic product became effective: June 24, 1986. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was June 24, 1986.

2. The date the application was initially submitted with respect to the human drug product under section 351 of the Public Health Service Act: September 1, 1987. FDA has verified the applicant's claim that the date PLA 87-0406 became effective was September 1, 1987.

3. The date the application was approved: December 17, 1991. FDA has verified the applicant's claim that PLA 87-0406 was approved December 17, 1991.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Douglas P. Mueller
Wegner, Cantor, Mueller & Player
P.O. Box 18218
Washington, D.C. 20036-8218